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K 962036

II.510(k) SUMMARY**A. General Information**

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Company Name and Address Medtronic, Inc.
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Submission Date 5/8/96

B. Device Name and Classification

Device Generic Name Transvenous screw-in pacing lead

Device Trade Name Medtronic model 5058 Bipolar, Implantable, Screw-In, Ventricular/Atrial, Transvenous Lead

Classification Name and Number Permanent Pacemaker Electrode
21 CFR, Part 870.3680

C. Predicate Devices

Device	510(k) Number / Approval Date
Medtronic model 4558M Bipolar, Implantable, Screw-In, Atrial, Transvenous Lead	K940703 / November 1994
Medtronic model 4058M Bipolar, Implantable, Screw-In, Ventricular/Atrial, Transvenous Lead	K883743 / January 1989

D. Device Description

The Medtronic model 5058 transvenous screw-in pacing lead has a helical tip electrode made of platinum alloy that can be actively fixed in the endocardium. The helix can be extended or retracted by rotating the lead connector pin with a fixation tool. This lead also has a second, larger electrode proximal to the tip electrode and an IS-1 Bipolar connector with one terminal pin. It features MP35N nickel-alloy coil conductors and silicone rubber insulation.

E. Intended Use

The model 5058 screw-in lead is indicated for pacing and sensing applications in either the atrium or the ventricle. This lead has application where implantable permanent atrial or ventricular, single chamber or dual chamber pacing systems are indicated. This permanent pacemaker lead is used to provide channeled electrically conductive pathways between the pulse generator and the heart.

F. Technology Comparison

The new model 5058 lead and the currently available model 4558M and 4058M leads all have extendible/retractable helix electrode lead tips. These tips act as the cathode electrodes for all three bipolar leads. The anodes for these leads consist of ring electrodes proximal to the helix. All electrodes for all leads are made of the same material, Platinum -Iridium (Pt-Ir).

The cathodes and anodes for all three leads are connected to conductor coils made of MP35N nickel-alloy. The MP35N conductor coils for the model 4558M and 4058M leads are platinum sputtered whereas the coils for the model 5058 lead are not sputtered.

The reason the model 5058 coils are not sputtered is because the inner and outer insulation material for the model 5058 lead is silicone rubber. The insulation material for the model 4558M and 4058M leads is polyurethane.

The conductor coils for all three leads terminate at the proximal end of the leads in the standard bipolar IS-1 (International Connector Standard ISO 5841-3:1992[E]) configuration. Furthermore, all three leads utilize 9 French introducers for access into the venous system.

G. Summary of Studies

Mechanical, electrical and canine testing was performed to evaluate the model 5058 lead. Testing previously provided for the models 5024/5524 (P950089/S9) regarding the surface treatment of the silicone insulation and the biostability of the insulation, is considered relevant to the 5058. Additionally, testing previously provided on the lead models identified below, regarding biocompatibility, is also considered relevant to the model 5058 lead:

Lead Model Number	Document Control Number	Approval Date
5023/5523	P850089/S6	November 1988
5024/5524	P850089/S9	December, 1989
5024M	P850089/S15	December, 1990
5524M	P850089/S16	December , 1991
4057/4557	K882452	August, 1988
4058	K883743	January, 1989
4558M	K940703	November, 1994
5028	K933731	March, 1994

Testing performed on the model 5058 included:

I. Environmental Conditioning

1. EtO sterilization,
2. Thermal shock,

II. Mechanical Testing

1. Helix electrode extension/retraction testing,
2. Connector mating,
3. Tip pressure testing,
4. Leak testing,
5. Joint and composite pull strength,
6. Composite torsional strength,
7. Anchoring sleeve suture test,
8. Flex testing,
9. Stylet insertion/withdrawal testing,

III. Electrical Testing

1. Resistance,
2. IS-1 offset block/AC impedance testing,

IV. Tip-to-ring Spacer Testing

V. *In-vivo* (canine) electrical performance testing

All of the testing performed on the model 5058 lead, and previously submitted testing on the model 5024/5524, and the lead models identified above for biocompatibility testing, demonstrate that the model 5058 will perform to Medtronic specifications.

H. Conclusion

The bench testing presented herein, along with the testing provided previously on the lead models identified above, provide reasonable assurance that the Medtronic model 5058 lead will perform as intended when used in accordance with its labeling. Additionally, based on similarities in design, materials, in vitro test data and *in vivo* electrical performance, the model 5058 is considered substantially equivalent to the model 4558M and model 4058M leads.